PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 503/04147	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IL05/00871	International filing date *(day/month/year)* 11 August 2005 (11.08.2005)	Priority date *(day/month/year)* 12 August 2004 (12.08.2004)
International Patent Classification (IPC) or national classification and IPC IPC: G01N 23/20(2006.01) USPC: 250/303		
Applicant NAVOTEK MEDICAL LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06 June 2007 (06.06.2007)	25 March 2008 (25.03.2008)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer David A. Vanore Telephone No. 571-272-2483

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL05/00871

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3(a) and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:
pages 1-29 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 30-35 received by this Authority on 06 June 2007 (06.06.2007)
pages* NONE received by this Authority on

☒ the drawings:
pages 1-12 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages none
☒ the claims, Nos. NONE
☒ the drawings, sheets/figs NONE
☒ the sequence listing (*specify*): NONE
☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

5. ☐ This report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No
PCT/IL05/00871

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-35	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-35	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-35	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-35 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the invention recited in claim 1-35. Applicant's amendment to the claims and the remarks submitted June 6, 2007 appear to successfully traverse the position taken by the Examiner. The Examiner finds the remarks persuasive.

Claims 1-35 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Replacement Sheet

CLAIMS

1. A computerized system for tracking and locating a source of ionizing radiation, the system comprising:

(a) at least one non-imaging sensor module comprising at least one radiation detector, said at least one radiation detector capable of receiving ionizing radiation from the radiation source and producing an output signal; and

(b) a CPU designed and configured to receive said output signal and translate said output signal to directional information regarding the location of the source relative to said at least one detector.

2. The system of claim 1, wherein the source of radiation is integrally formed with or attached to a medical device.

3. The system of claim 1, wherein said at least one sensor module includes at least two sensor modules.

4. The system of claim 3, wherein said at least two sensor modules includes at least three sensor modules.

5. The system of claim 1, wherein at least one of said at least one sensor module further comprises a locomotion device, said locomotion device capable of imparting translational motion to said sensor module so that said sensor module is moved to a new location.

6. The system of claim 5, wherein said locomotion device is operable by a translational motion signal from said CPU.

7. The system of claim 1, additionally comprising:

(c) an imaging module, said imaging module capable of providing an image signal to said CPU, said CPU capable of translating said image signal to an image of a portion of the body of the subject.

8. The system of claim 1, further comprising a display device.

9. The system of claim 7, further comprising a display device.

10. The system of claim 9, wherein the source of radiation is integrally formed with or attached to a medical device and wherein said display device is capable of displaying said image of said portion of the body of the subject with a determined position of the medical device superimposed on said image of said portion of the body of the subject.

11. The system of claim 1, wherein said CPU receives at least two of said output signals and computes a position of said radiation source based on said output signals.

12. The system of claim 1, wherein said CPU receives at least three of said output signals and computes a position of said radiation source based on said at least three output signals.

13. The system of claim 12, wherein said CPU computes said position repeatedly at intervals so that a position of said radiation source as a function of time may be plotted.

14. The system of claim 1, wherein said radiation source employs an isotope with a half life in the range of 6 to 18 months.

15. The system of claim 1, additionally comprising said radiation source capable of providing said radiation.

16. The system of claim 1, wherein said directional information is produced when the source has an activity in the range of 0.01 mCi to 0.5 mCi.

17. A sensor for directionally locating an ionizing radiation source, the sensor comprising:

(a) at least one functional component; and

(b) a displacement mechanism which imparts angular sensitivity to the sensor by moving said at least one functional component.

18. A sensor according to claim 17, wherein said at least one functional component comprises at least one radiation detector, said at least one radiation detector capable of receiving radiation from the radiation source and producing an output signal;

wherein said displacement mechanism is capable of rotating said at least one radiation detector through a rotation angle so that said output signal varies with said rotation angle.

19. The sensor of claim 18, wherein said at least one radiation detector comprises at least one first radiation detector and at least one second radiation detector and said output signal comprises at least one first output signal from said at least one first radiation detector and at least one second output signal from said at least one second radiation detector.

20. The sensor of claim 19, additionally comprising at least one radiation shield installed at a fixed angle with respect to said at least one first radiation detector and said at least one second radiation detector so that a magnitude of said first output signal from said at least one first radiation detector and a magnitude of said second output signal from said second radiation detector vary with said rotational angle.

21. A sensor according to claim 17, comprising:

(a) at least one first radiation detector and at least one second radiation detector, each of said at least one first radiation detector and at least one second radiation detector capable of receiving radiation from the radiation source and

producing at least one first output signal from said at least first radiation detector and at least one second output signal from said at least second radiation detector; and

(b) at least one radiation shield rotatable about an axis of shield rotation through an angle of shield rotation, so that a magnitude of said first output signal from said at least one first radiation detector and a magnitude of said second output signal from said at least one second radiation detector each vary with said angle of shield rotation.

22. A sensor according to claim 20, wherein said at least one radiation shield comprises:

(i) a primary radiation shield located between said at least one first radiation detector and said at least one second radiation detector;

(ii) at least one first additional radiation shield deployed to interfere with incident radiation directed towards said at least one first radiation detector; and

(iii) at least one second additional radiation shield deployed to interfere with incident radiation directed towards said at least one second radiation detector.

23. The sensor according to claim 22, wherein said at least one first additional radiation shield and said at least one second additional radiation shield are each inclined towards said primary radiation shield.

24. A sensor according to claim 22, wherein said at least one first radiation detector and said at least one second radiation detector are organized in pairs, each pair having a first member and a second member and each radiation shield of said primary and additional radiation shields is located between one of said first member and one of said second member of one of said pairs so that said output signal varies with said rotation angle.

25. The sensor of claim 17, additionally capable of revolving said at least a functional component about an axis of revolution through an angle of revolution.

26. A method of determining a location of a device, the method comprising:

(a) providing a device having a radiation source associated therewith;

(b) determining a direction towards said radiation source;

(c) further determining at least a second direction towards said radiation source; and

(d) locating said device by calculating an intersection of said first direction and said at least a second direction.

27. The method of claim 26, wherein said further determining at least a second direction towards said radiation source includes determining at least a third direction towards said radiation source and additionally comprising:

(e) calculating a point of intersection of said first direction, said second direction and said at least a third direction.

28. A method of manufacturing a trackable medical device, the method comprising incorporating into or fixedly attaching a detectable amount of a radioactive isotope to the medical device.

29. The method of claim 28, wherein said detectable amount is in the range of 0.01 mCi to 0.5 mCi.

30. The method of claim 28, wherein said detectable amount is 0.1 mCi or less.

31. The method of claim 28, wherein said detectable amount is 0.05 mCi or less.

32. The method of claim 28, wherein said isotope is Iridium-192.

33. The use of an ionizing radiation source with an activity of 0.1 mCi or less as a target for non imaging localization or tracking.

34. The use of an ionizing radiation source according to claim 33, wherein said non imaging or tracking is performed on an implantable medical device.

35. A system according to claim 1, wherein each of said at least one sensor module includes a functional component and a rotation mechanism; and wherein said CPU is designed and configured to calculate gamma ray impacts from the source for a period of time and to determine, based on the total output for each of said at least one sensor module, in which direction and to what degree to rotate said at least one sensor module.